UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456 CIVIL ACTION : 01-CV-12257-PBS (Subcategory Docket: 06-11337)
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

VEN-A-CARE'S REPLY TO ABBOTT LARBORATORIES INC.'S RESPONSE TO VEN-A-CARE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

The arguments made by Abbott in its response to do not preclude this Court from granting Plaintiffs' Motion for Partial Summary Judgment. Among other things, Abbott has not identified a genuine issue of material fact. To clarify the record, Plaintiff replies to several points Abbott has raised in its Response to Ven-A-Care's Motion for Partial Summary Judgment.

I. ABBOTT REPORTED FALSE PRICES FOR ITS ERY PRODUCTS AND ATTEMPTED TO INDUCE UTILIZATION OF ITS PRODUCTS BASED ON THE SPREAD IT CREATED

Unlike in Abbott's Hospital Products Division (HPD), whose products are at issue in the intervened case against Abbott, for most PPD (Pharmaceutical Product Division) products, WAC was actually reflective of net transaction prices. For the PPD Erythromycin ("Ery") products, however, the published WAC was not reflective of net transaction prices. *See* Plaintiff's Local Rule 56.1 Statement of Undisputed Material Facts, Dkt. #6417 (hereinafter "VAC-ERY-SF"), ¶¶ 6-8; 17-18. This dichotomy was the result of Abbott's reporting of misleading WAC pricing for the Erys and the concealment of actual gross wholesale invoice prices known as Base Deal pricing on the Erys. *Id*.; *see also* VAC-ERY-SF ¶¶ 19, 20, 37, 44, 46. Abbott admits that sales at published WAC prices for the Ery drugs were rare, which contrasted

sharply with the other PPD drugs. *See* VAC-ERY-SF ¶¶8, 17. Tellingly, this atypical PPD price reporting for the Ery drugs occurred in a market that was characterized by competition and susceptible to spread inducements, unlike most of the PPD market.

Abbott's argument about the percentage of customers to which sales were made at list price or WAC is misleading. *See* Abbott's Response to Ven-A-Care's Motion for Summary Judgment, Dkt. # 6632 (hereafter "Abbott's Response"), at 4. As its corporate representative testified, no more than five to ten percent of Abbott's sales of erythromycin products were at these prices. *See* 12/17/09 Fiske Tr. 48:12-25, (Declaration of Susan Schneider Thomas in Support of Plaintiffs' Motion for Partial Summary Judgment, Dkt. #6422 (hereinafter "Thomas") Ex. 54); *see also* 12/17/09 Fiske Tr. 63:15-25; Berlin Declaration, Dkt. #6640, Ex. 2. Further, PPD's lower Base Deal prices were discontinued in 2003, *see* 12/17/08 Garvin-Senger Tr. at 201:16-201:21 (Thomas Ex. 1), causing sales to wholesalers to be made at inflated published WACs and resulting in the increase of relative dollar value of chargebacks processed after 2003. *See* 12/17/08 Garvin-Senger Tr. at 201-202 (Thomas Ex. 1); 12/17/08 Garvin-Senger Tr. Ex. 13 (Thomas Ex. 11)(stating "[w]e have decided not to offer the 'Base Deal' price any longer. . . invoice price will now be using the WAC price[;] . . . [t]his will result in higher chargebacks, but the wholesalers will also be receiving a higher dollar amount on their purchases due to the 2% cash discount and 1% returned goods allowance will now be on a higher price."); 1/22/09 Pavlik Tr. Ex. 17 (Thomas Ex. 11).

Abbott also argues it did not set AWPs. *See* Abbott's Response at 6. As set forth in the United States' Memorandum of Law in Support of Cross Motion for Partial Summary Judgment and in Opposition to Abbott's Motion for Summary Judgment, incorporated herein by reference, this assertion is incorrect. Dkt. #6319, 11-13.

Additionally, Abbott refers to a number of government reports which allegedly revealed spreads on the Ery drugs. These reports either do not identify the Abbott Ery drugs or do not show true prices for Abbott's Ery drugs and did not provide the government with usable information about the true prices for these drugs. For example, at the 1992 Congressional hearing, directly contrary to Abbott's assertions, the National Association of Retail Druggists (NARD) presented testimony that the prices shown were contract prices available to hospitals, which were **not available** to retail pharmacies (NARD's members). NARD clearly stated these "hospital" prices "were discounted beyond the amount (AWP-15%) that might be available to retail pharmacists . . . (a)ny way you slice it our members are getting a raw deal." *See* Plaintiffs Response to Abbott Local Rule 56.1 Statement of Undisputed Material Facts in Support of Abbott's Motion for Partial Summary Judgment. Dkt. # 6622, ¶20. The government reports cited are also irrelevant for purposes of summary judgment as none of them demonstrate government approval of, or even acquiescence in, Abbott's false price reporting. *Id*. at ¶¶16-33.

The record shows that Abbott marketed the spread by communicating AWP information in documentation such as product listings, order sheets, sell sheets and stocking sheets. *See* 1/15/09 Lehn Tr. Ex. 9 (Declaration of C. Jarrett Anderson in Support of Plaintiffs' Response to Abbott's Motion for Partial Summary Judgment, Dkt # 6625 (hereinafter "Anderson"), Ex. 20); 1/15/09 Lehn Tr. Ex. 11 (Thomas Ex. 26); 1/15/09 Lehn Tr. at 127:1-131:11 (Thomas Ex. 10).

Finally, Abbott's arguments based on AMPs or FULs are unavailing. The reporting of AMPs does not negate Abbott's scienter for the reasons set forth in the United States' Memorandum of Law in Support of Cross Motion for Partial Summary Judgment and in Opposition to Abbott's Motion for Summary Judgment. Dkt. # 6319 at 25 (arguing, *inter alia*, that this Court has already rejected an AMP theory as a basis for a government knowledge

defense asserted in *Commonwealth of Massachusetts v. Mylan*, 608 F. Supp. 2d 127 (D. Mass. 2008)). Further, the existence of MACs or FULs does not help Abbott because FUL or MAC prices do not exclusively form the basis for Medicaid reimbursement, even when FUL or MAC prices are in place. As a function of state Medicaid programs' almost universal use of "lower of" reimbursement methodologies, Abbott's reporting of truthful published prices that reflected market prices paid by pharmacies would have resulted in EACs lower than an applicable FUL or MAC for a given drug reimbursement calculation in virtually every instance where a FUL or MAC was actually used to determine the reimbursement amount. *See* Brief of the United States on the Federal Upper Limit (Dkt. # 4413) and Supplemental Brief of the United States on the Federal Upper Limit (Dkt. # 6693). In any event, Plaintiff only attributed damages to Abbott in instances where that was the case. *See* Duggan Declaration at ¶¶ 26, 29,31 (Anderson Ex. 33).

II. VEN-A-CARE HAS ESTABLISHED A FALSE AND FRAUDULENT CLAIM AS REQUIRED BY THE FCA

A claim can be facially true and still be a false claim for purposes of the FCA. The reasoning of *United States ex rel. Debra Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25 (D.D.C. 2007), discussed at length by Abbott in its brief, has been rejected by the First Circuit and by this Court.

In *United States v. Dynamics Research Corp*, 2008 U.S. Dist. Lexis 25354 (D. Mass. 2008), the court granted summary judgment as to liability even though DRC argued that the claims themselves accurately reflected what the government paid and had received. In that case, defendant had supplied computer memory capacity at a significant markup although market prices for memory had fallen drastically. The court noted that history as well as the weight of precedent supported the government's position that false claims are not limited to those that are false on their face:

> Since the Civil War, the FCA has been used to ferret out all types of fraud resulting in claims for government funds, not just for claims that are false on their face.

Id. at *28. Thus, a claim undermined by fraud can violate the FCA "even if it is facially accurate." *Id.* at *30. *See also United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (defendant liable where claim filed by third party not false but inflated by defendant's earlier fraud); *United States ex rel. Marcus v. Hess*, 317 US 537, 543-44 (1943) (claims deemed fraudulent not from information on their face but from collusive bids underlying them).

Similarly, in *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist Lexis 15754 (D. Mass. 2003), this Court found that a Medicaid reimbursement request for an off-label prescription was a false claim. Here, as in *Parke-Davis*, it was foreseeable that Abbott's reporting of false AWPs "'caused to be presented' a false claim," *id.*, at *6, under 31 U.S.C. § 3729.

III. THE MEANING OF AWP IS A LEGAL QUESTION, WHICH DOES NOT PRECLUDE SUMMARY ADJUDICATION OF THE CLAIMS ASSERTED AGAINST ABBOTT

Abbott disingenuously argues that this Court should use a payor expectation standard to define AWP, as was done in the MDL class case involving private third-party payors. *See* Abbott Response at 19. The key here, however, is that the terms AWP and WAC in the Medicaid context are derived from statutes and regulations, not private contracts, and principles of statutory construction apply rather than contract interpretation. For example, under a contract, even with the government, the course of communications and conduct may indicate a modification of the terms; however, this is not the case when interpreting a statute or regulation. *Contrast United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 454 n.21 (6th Cir. 2005) (government knowledge may negate scienter under the FCA where it is used "to demonstrate that what the defendant submitted was not actually false but rather

conformed to a modified agreement with the Government"); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir.), *cert. denied*, 508 U.S. 973, 125 L. Ed. 2d 663, 113 S. Ct. 2962 (1993) (government knowledge may be relevant to "show that the contract has been modified or that its intent has been clarified, and therefore that the claim submitted by the contractor was not 'false'") *with United States v. Boeing Co*., 802 F.2d 1390, 1393 (Fed. Cir. 1986) ("The interpretation of regulations which are incorporated into government contracts is a question of law which this court is free to resolve."). The economic analysis of the evolving expectations of private market entities is simply not applicable as a canon of statutory construction. Abbott blithely ignores this crucial difference and cites no authority for the proposition that an examination of legislative intent – if even that is called for – would proceed in the open market sense of economic analysis.

Instead, as this Court and the First Circuit have previously determined, the determination of the meaning of AWP in the Medicaid context follows settled principles of reliance on the plain meaning of the statutory terms. *See In re Pharmaceutical Average Wholesale Price Litigation*, 460 F. Supp. 2nd 277 (D. Mass. 2006), *aff'd*, 582 F.3d 156, 168 (1st Cir. 2009). Second, this Court has already found that AWP did not have an "established and settled meaning" in the industry and therefore was not a used as a "term of art." *In re Pharm. Indus. Average Wholesale Price Litig*., 460 F. Supp. 2d, 277, 285 (D. Mass. 2006), *aff'd*, 582 F.3d 156, 170 (1st Cir. 2009). Furthermore, in the context in which the term AWP appears – as a means to determine a Medicaid program's best estimate of the price generally and currently paid by providers for a drug product – it is clear that the term was used with its plain meaning as an average of the net prices that wholesalers charges providers. CMS' or Congress' "expectations" about the extent to which average actual prices are below the manufacturers' reported AWPs

simply has no place in this analysis. Finally, Abbott's contention that AWP should be construed to mean essentially any amount it chooses as a List Price, regardless whether that price had any relation to the amount providers were paying in the competitive market place, would lead to absurd results totally at odds with the intent of the Medicaid program. *Id.* at 287; *In re Pharmaceutical Average Wholesale Price Litigation*, 582 F.3d at 170 n. 9.

Abbott's argument that summary judgment is precluded because the term AWP might be interpreted as an undiscounted list price, (Abbott Response at 22), totally misses the boat. Disputes about legal issues – as compared to factual disputes – do not preclude summary judgment. As noted above, the meaning of the term AWP in the federal statutes and regulations is a matter of law, not fact. *See Cmtys. for Equity v. Mich. High Sch. Ath. Ass'n*, 459 F.3d 676, 680 (6th Cir. 2006) ("[c]onstitutional and statutory interpretation questions are issues of law"); *Rumsfeld v. United Techs. Corp*., 315 F.3d 1361, 1369 (Fed. Cir. 2003) ("The views of the self-proclaimed CAS experts, including professors of economics and accounting, a former employee of the CAS Board, and a government contracts accounting consultant, as to the proper interpretation of those regulations is simply irrelevant to our interpretive task; such evidence should not be received, much less considered, by the Board on the interpretive issue[;] . . . [t]hat interpretive issue is to be approached like other legal issues - based on briefing and argument by the affected parties."); *Gen. Elec. Co. v. Delaney*, 251 F.3d 976, 978 (Fed. Cir. 2001) ("federal procurement law, [and] the board's conclusions of law, such as the meaning of a regulation or statute, are reviewed de novo"). There are accepted canons of statutory construction that the Court applies, normally without regard to any facts, let alone disputed facts. Even defendant's argument that the term AWP was adopted as an industry term of art is a legal question to be resolved by the Court. While it is true that the Court may examine facts to see whether there

was, indeed, an industry-wide definition of the term, and whether Congress or CMS intended to adopt that industry definition, these are still legal rulings to be made by the Court. There is no basis on which to defer this decision past summary judgment, as this Court has expressly ruled previously. As this Court summarized the proceedings:

> Prior to trial on the claims against the Track 1 defendants, the district court entertained cross-motions for summary judgment arguing the meaning of the term 'average wholesale price' in the Medicare statute, 42 U.S.C. § 1395u(o) (1998). In November 2006, the district court construed the statutory term to mean the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies, and including discounts and rebates.

In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d at 287. This approach was approved by the appellate court. *Blue Cross and Blue Shield v. AstraZenecca Pharms. LP*, 582 F.3d 156, 165-70 (1st Cir. 2009). Abbott's effort to avoid a ruling on summary judgment, therefore, must be rejected.

CONCLUSION

For the foregoing reasons and for the reasons set forth in Ven-A-Care's Motion for Partial Summary Judgment, Ven-A-Care requests that the Court grant it summary judgment as to liability, specifically on the elements of falsity, materiality, causation and scienter on its FCA Medicaid claims, and summary judgment on the enumerated Affirmative Defenses.

Respectfully submitted,

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